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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,547	08/08/2001	Andrew Grupe	ROCH-007	4701

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EXAMINER

GUCKER, STEPHEN

ART UNIT	PAPER NUMBER
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1647

12

DATE MAILED: 12/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/925,547

Applicant(s)

GRUPE ET AL.

Examiner

Stephen Gucker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-11 and 16-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Applicant's election with traverse of Group IV, claims 12-15, filed 5/22/03 is acknowledged. The traversal is on the ground(s) that the search is not unduly burdensome because Groups III, IV, and V share the feature of detecting CaCC activity. This is not found persuasive because the searches for screening assays that use cell free systems, use whole cells or tissues, or use immobilization on a solid support are classified separately and involve separate and non-overlapping searches for each. For example, the anticipatory prior art cited in this Office Action would not be anticipatory art in either a cell free system or an immobilization system on a solid support. Furthermore, the enablement issues are separate and distinct for each Group. While the CaCC ion channel of the instant invention may function in a cell free lipid bilayer system or in a whole cell or tissue, separate enablement issues arise when one tries to make and use a screening method employing a physiological ion channel immobilized on a solid support.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-11 and 16-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the election filed 5/22/03.

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37

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CFR 1.821 through 1.825 for these reason(s): Pages 39-40 of the specification contains Table I which is illegible because the right side of the table runs off the printed page. In addition, the sequences in this table are missing the required SEQ ID NOs. A new legible table must be submitted that contains SEQ ID NOs for the sequences therein.

4. Applicant is given the shortened statutory period of THREE MONTHS from the mailing date of this letter within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 12-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The disclosure fails to describe the amino acid sequence of any CaCC, it does not describe the critical polypeptide domains that bestow upon the CaCC its desired biological function, and it does not describe any fragments of any CaCC that have biological function. Likewise, the hCLCA1 is not

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adequately described. Therefore, the instant method claims encompassing the use of fragments of CaCC in order to identify agonists or antagonists of CaCC activity are not adequately described by the instant specification because the specification is silent as to what fragments of any CaCC possess biological activity as required by the instant claim language. The grounds of this rejection could be obviated by removing the fragment language from the instant claims.

6. Claims 12-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the unfragmented CaCC, does not reasonably provide enablement for a fragment thereof of CaCC. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The disclosure fails to set forth the amino acid sequence of any CaCC, it does not teach the critical polypeptide domains that bestow upon the CaCC its desired biological function, and it does not provide any examples of any fragments of any CaCC that have biological function. Likewise, the hCLCA1 is not adequately enabled for the use of its fragments. Therefore, the instant method claims encompassing the use of fragments of CaCC in order to identify agonists or antagonists of CaCC activity are not adequately supported by the instant specification because the specification is silent as to what fragments of any CaCC possess biological activity as required by the instant claim language. The grounds of this rejection could be obviated by removing the fragment language from the instant claims.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Gandhi et al. ("Gandhi"). Gandhi discloses the use of mCLCA1 in transfected HEK293 cells and the effects of ionomycin, DIDS, NFA, and DTT on mCLCA1 activity (pages 32099-32100 and Figures 5 and 6).

8. Claims 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Gruber et al. ("Gruber"). Gandhi discloses the use of hCLCA1 in transfected HEK293 cells and the effects of ionomycin, DIDS, NFA, and DTT on mCLCA1 activity (pages 209-211 and Figures 7, 8, and 9).

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Stephen Gucker

12/18/03


GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600